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# GAIN Report

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## Slovenia

### Biotechnology

### Status of Biotech Regulations

**2003**

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**Report Highlights:**

This report provides an overview of the current regulatory environment for biotechnology and includes contact information for the Ministries and Agencies that monitor and enforce biotech regulations.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Vienna [AU1]  
[SI]

## Relevant Laws and Regulations Governing Biotech Products

Act Regulating Handling With Genetically Modified Organisms (Official gazette RS 67/2002), Effective since 8/10/2002.

Act Regulating the Sanitary Suitability of Foodstuff, Products and Materials Coming into Contact with Foodstuffs (official gazette RS 52/2000; 42/2002), effective since 06/28/2000

Rules On The Labeling Of Foodstuffs Produced From Genetically Modified Soy And From Genetically Modified Maize (Official gazette RS 105/2002), Effective since 12/20/2002, some articles become effective 1.1.2004

Regulation On Labelling Foodstuff And Ingredients Containing Genetically Modified Additives And Aroma, Or Are Produced From Genetically Modified Organisms (Official gazette RS 105/2002), Effective since 12/20/2002, some articles become effective 1.1.2004

## Regulatory Process For Approving Products For Import And Sale.

The process for approving products for import and sale is defined by the "Law On Handling With Genetically Modified Organisms". Before a product is put on the market (for sale) for the first time, the seller must obtain permission from the Ministry of Environment. Applicant must provide a risk assessment study for a product before applying for permission. The application must contain:

- technical documentation including:
  - i. commercial name
  - ii. producer, importer or distributor
  - iii. person responsible for sample control
  - iv. intended use of the product
  - v. geographical area in type of the environment where product is intended to be used
  - vi. potential users of the product
- risk assessment
- terms of putting product on the market including specific terms of its use and handling
- program of monitoring of products influence on the environment
- period of validity of the permission
- how the product will be labelled showing the GMO containment
- how the product will be packed.

Before importing a biotech product, permission for putting the product on the market must be obtained. The government will define additional import conditions (not yet available).

## Departments And Ministries Enforcing Biotech Regulations

The main responsibility goes to Ministry Of Environment, Spatial Planning And Energy, which cooperates with Ministry Of Health And Ministry Of Agriculture, Forestry And Food. Also the monitoring is divided among departments belonging to these ministries, including: Office For Foodstuff And Nutrition, Environmental, Health, Agricultural, Veterinary And Market Inspection. The analysis on GMO containment in foodstuff is done at National Institute Of Biology.

### Government Enforcement and Penalties

The monitoring institution/inspector can prohibit or temporarily cease trade or use the product. For non-compliance, the penalty is between \$1500 and \$150,000

### Testing for Biotech Content

Each importer must file a claim and check on health requirements for every foodstuff shipment. A random check on biotech content can be performed

### Traceability

At present, the law only requires registration of a biotech product, which includes basic data about firm, and address of the applicant; and a listing of issued permissions and approvals for putting the product in the environment or on the market. For products on the market, a label showing that the product "contains GMO" is required

### In-Country Field Test:

At present, not required.

### Labelling

All food products containing more than 1 percent biotech content must be labelled. Label must contain the text "izdelano iz gensko spremenjenega ... (name of the GMO)" – produced from genetically modified.

At present, there is no legislation preventing use of GMO-free labels.